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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/681,609	10/08/2003	Christopher B. Eckman	07039-281002	7406
26191	7590	05/06/2004	EXAMINER	
FISH & RICHARDSON P.C. 3300 DAIN RAUSCHER PLAZA 60 SOUTH SIXTH STREET MINNEAPOLIS, MN 55402			COE, SUSAN D	
			ART UNIT	PAPER NUMBER
			1654	

DATE MAILED: 05/06/2004

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.

10/681,609

Applicant(s)

ECKMAN ET AL.

Examiner

Susan Coe

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☐ Responsive to communication(s) filed on ____.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☐ Claim(s) 35 and 36 is/are pending in the application.
- 4a) Of the above claim(s) ____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) ____ is/are allowed.
- 6) ☒ Claim(s) 35 and 36 is/are rejected.
- 7) ☐ Claim(s) ____ is/are objected to.
- 8) ☐ Claim(s) ____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on ____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. ____.
 3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- * See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- 1) ☒ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) ☐ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)
Paper No(s)/Mail Date ____.
- 4) ☐ Interview Summary (PTO-413)
Paper No(s)/Mail Date. ____.
- 5) ☐ Notice of Informal Patent Application (PTO-152)
- 6) ☐ Other: ____.

DETAILED ACTION

1. The preliminary amendment filed October 8, 2003 has been received and entered.
2. Claims 1-34 have been cancelled.
3. Claims 35 and 36 have been added.
4. Claims 35 and 36 are currently pending and are examined on the merits.

Claim Rejections - 35 USC § 102

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

5. Claims 35 and 36 are rejected under 35 U.S.C. 102(b) as being anticipated by US Pat. No. 5,916,565.

Applicant's claims are drawn to a composition comprising an "active fraction" of a *Cimicifuga* extract and a pharmaceutically acceptable carrier.

US '565 teaches a composition that comprises black cohosh (a *Cimicifuga* sp.) and substances that are pharmaceutically acceptable carriers such as palatability agents (see claims). The reference does not specifically teach that the black cohosh contains an "active fraction" as claimed by applicant. However, applicant's specification discloses that the "active fraction" is found in any *Cimicifuga* species. Thus, the black cohosh composition of US '565 is a composition that comprises an active fraction as described by applicant.

The reference also does not specifically teach that the composition has the same effects on the body as those claimed by applicant; however, since the composition taught by the reference is the same as the claimed composition, the reference composition would inherently have to have the same effects if applicant's invention functions as claimed.

Furthermore, the reference does not teach that the composition is labeled and packaged as claimed by applicant. However, written instructions reciting an alleged novel use of a composition do not change the composition itself. *See, e.g., In re Haller* 73 USPQ 403, at 404 (CCPA 1947) ("Accordingly, the mere labeling of an old composition as an insecticide does not make it a new or different composition within the meaning of the patent statutes.").

6. Claims 35 and 36 are rejected under 35 U.S.C. 102(b) as being anticipated by Lieberman (*Journal of Woman's Health* (1998), vol. 7, no. 5, pp. 525-529).

Lieberman teaches pharmaceutical compositions comprising extracts from *Cimicifuga racemosa* (black cohosh). The reference does not specifically teach that the black cohosh contains an "active fraction" as claimed by applicant. However, applicant's specification discloses that the "active fraction" is found in any *Cimicifuga* species. Thus, the black cohosh composition of US '565 is a composition that comprises an active fraction as described by applicant.

The reference also does not specifically teach that the composition has the same effects on the body as those claimed by applicant; however, since the composition taught by the reference is the same as the claimed composition, the reference composition would inherently have to have the same effects if applicant's invention functions as claimed.

Furthermore, the reference does not teach that the composition is labeled and packaged as claimed by applicant. However, written instructions reciting an alleged novel use of a composition do not change the composition itself. *See, e.g., In re Haller* 73 USPQ 403, at 404 (CCPA 1947) (“Accordingly, the mere labeling of an old composition as an insecticide does not make it a new or different composition within the meaning of the patent statutes.”).

7. Claims 35 and 36 are rejected under 35 U.S.C. 102(b) as being anticipated by US Pat. No. 4,469,685.

US ‘685 teaches a composition extracted from *Cimicifuga* species. The plant is first extracted with water and then with a solvent such as butanol (see claims 1, 9, and 10). Numerous different *Cimicifuga* plants can be used (see claim 12, lines 44-47). The extract is coupled with a pharmaceutically acceptable carrier such as water (see column 16, line 5). Applicant’s specification describes extracting the “active fraction” from *Cimicifuga* by first extracting the plant using aqueous extraction and then further extracting the extract with a solvent such as butanol (see pages 11 and 12). Thus, the composition taught by US ‘685 would contain an “active fraction” as claimed by applicant.

The reference also does not specifically teach that the composition has the same effects on the body as those claimed by applicant; however, since the composition taught by the reference is the same as the claimed composition, the reference composition would inherently have to have the same effects if applicant’s invention functions as claimed.

Furthermore, the reference does not teach that the composition is labeled and packaged as claimed by applicant. However, written instructions reciting an alleged novel use of a composition do not change the composition itself. *See, e.g., In re Haller* 73 USPQ 403, at 404

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(CCPA 1947) (“Accordingly, the mere labeling of an old composition as an insecticide does not make it a new or different composition within the meaning of the patent statutes.”).

8. Claims 35 and 36 are rejected under 35 U.S.C. 102(b) as being anticipated by Japanese Pat. Pub. No. 09-030977.

JP ‘977 teaches a composition extracted from a *Cimicifuga* species. The plant material is extracted first with a solvent such as methanol or ethanol and then with a solvent such as hexane, ethyl acetate or butanol (see paragraph [0041] - [0046] of the English translation). The extract is combined with carriers (see paragraph [0085] of the English translation). Applicant’s specification describes extracting the “active fraction” from *Cimicifuga* by first extracting the plant using solvents such as ethanol and then further extracting the extract with a solvent such as hexane, ethyl acetate, or butanol (see pages 11 and 12). Thus, the composition taught by JP ‘977 would contain an “active fraction” as claimed by applicant.

The reference also does not specifically teach that the composition has the same effects on the body as those claimed by applicant; however, since the composition taught by the reference is the same as the claimed composition, the reference composition would inherently have to have the same effects if applicant’s invention functions as claimed.

Furthermore, the reference does not teach that the composition is labeled and packaged as claimed by applicant. However, written instructions reciting an alleged novel use of a composition do not change the composition itself. *See, e.g., In re Haller* 73 USPQ 403, at 404 (CCPA 1947) (“Accordingly, the mere labeling of an old composition as an insecticide does not make it a new or different composition within the meaning of the patent statutes.”).


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9. No claims are allowed.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Susan Coe whose telephone number is (571) 272-0963. The examiner can normally be reached on Monday to Thursday from 8:00 to 5:30 and on alternating Fridays.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Brenda Brumback, can be reached on (571) 272-0961. The fax phone number for the organization where this application or proceeding is assigned is (703) 872-9306.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is (703) 308-0196.


Susan D. Coe, Examiner
April 26, 2004